



UNITED STATES PATENT AND TRADEMARK OFFICE

ck

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,298	12/10/1999	JOHN FIKES	18623-014600	8697

26111 7590 05/13/2005

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/458,298

Applicant(s)

FIKES ET AL

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41 and 49-63 is/are pending in the application.
- 4a) Of the above claim(s) 49, 51-55, 58, 60 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 41, 50, 56, 57, 59, 61, 62 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

RD

Art Unit: 1644

1. Claims 41,50,56,57,59,61,62 are under consideration.
2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
3. Claims 41,50,56,57,59,61,62 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,602,510 for the reasons elaborated in the previous Office action.
Applicant has requested that this issue will be held in abeyance until the indication of allowable claims.
4. Claims 41,50,56,57,59,61,62 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31,35-39 of copending Application No. 10/149915 for the reasons elaborated in the previous Office action.
Applicant has requested that this issue will be held in abeyance until the indication of allowable claims.

Art Unit: 1644

5. Applicant is required to update the status of all US applications disclosed in the specification.

6. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it discloses priority claims to applications to which priority is no longer claimed in the instant application.

Applicant has requested that this issue will be held in abeyance until the indication of allowable claims.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 41,50,56,57,59,61,62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent 5,342,774) in view of Rotzschke et al. and Rammensee et al. (WO 92/21033) as evidenced by Rammensee et al. (US Patent 5,747,269).

The Rammensee et al. (US Patent 5,747,269) reference is a 371 of WO 92/21033 and thus contains a certified English language translation of WO

92/21033 (German language publication). Thus, the Rammensee et al. (US Patent 5,747,269) patent is cited only in the context of providing a translation of WO 92/21033. Passages cited in the instant rejection will refer to the English language version of WO 92/21033 (US Patent 5,747,269), wherein said passages are found in WO 92/21033. Boon et al. teach MAGE 3, wherein the peptide KVAELVHFL is found in said protein (see Examples 23, 25, column 24, fourth paragraph). Boon et al. teach a nucleic acid encoding MAGE-3 with the appropriate delineated coding sequence (see Figure 20). The MAGE-3 amino acid sequence (derived from the aforementioned nucleic acid using the art known genetic code) contains peptide KVAELVHFL. Boon et al. teach that MAGE-3 is a TRAP which encodes TRA (tumor rejection antigen) wherein it is desirable to elucidate the identity of the actual peptide recognized by the CTL (see columns 23-26 and columns 3-4). Boon et al. do not teach the peptide KVAELVHFL. Rammensee et al. disclose that using a motif screening system that the identity of a tumor cell peptide reactive with CTL can be determined (see column 4 and abstract). Rammensee et al. disclose that HLA 0205 binds a 9mer peptide with an anchor residue of L at position 9. The claimed peptide has a L amino acid at position 9. Rammensee et al. teach compositions containing mixtures of such peptides wherein said composition would contain tissue culture media which would constitute a "pharmaceutically acceptable carrier" (see column 4, first incomplete paragraph). Rammensee et al. teach said peptide attached to linker amino acids (see column 5, first complete paragraph). Rotzschke et al. disclose that the such motifs can be used to scan protein sequences to identify T cell epitopes (see page 453, first column, third paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Boon et al. teach MAGE 3, wherein the peptide KVAELVHFL is found in said protein and that MAGE-3 is a TRAP which encodes TRA (tumor rejection antigen) wherein it is desirable to elucidate the identity of the actual peptide recognized by the CTL whilst Rammensee et al. disclose that using a motif screening system that the identity of a tumor cell peptide reactive with CTL can be determined and that HLA 0205 binds a 9mer peptide with an anchor residue of L at position 9 and Rotzschke et

al. disclose that the such motifs can be used to scan protein sequences to identify T cell epitopes.

Regarding applicants comments about Rammensee et al., Rotzschke et al. teach "Allele-specific consensus motifs can be used to scan protein sequences to identify T cell epitopes." (see page 453, first column, third paragraph). Thus, the art recognized that the allele-specific consensus motifs disclosed by Rammensee et al. can be used to scan protein sequences to identify T cell epitopes. Regarding applicants comments about the 9mer peptide motif with L at position 9, the amino acid sequence encoded by the Mage 3 nucleic acid only has about 30 potential peptides that would be encompassed by said motif. Producing said peptides and using said peptides in screening assays would be routine experimentation. Regarding applicants comments about Table 5 in Rammensee et al., the only position labeled as a "dominant anchor residue" is position 9. The other residues disclosed in said table are listed as other. The art recognizes that the peptide binding motif is characterized in view of the dominant anchor(s). For example, Rotzschke et al. present data regarding a Kd peptide binding motif in Figure 2. When Rotzschke et al. describe said motif in page 449, second column, last paragraph, said motif is described in terms of the dominant anchor positions (eg. residues 2/9 in this instance). Thus, the dominant anchor positions are the amino acids that define the MHC allele binding motif. Regarding applicants comments, the claimed peptide would be produced for screening purposes. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Boon et al. teach MAGE 3, wherein the peptide KVAELVHFL is found in said protein and that MAGE-3 is a TRAP which encodes TRA (tumor rejection antigen) wherein it is desirable to elucidate the identity of the actual peptide recognized by the CTL whilst Rammensee et al. disclose that using a motif screening system that the identity of a tumor cell peptide reactive with CTL can be determined and that HLA 0205 binds a 9mer peptide with an anchor residue of L at position 9 and Rotzschke et al. disclose that the such motifs can be used to scan protein sequences to identify T cell epitopes. Regarding applicants comments about motivation to create the claimed invention, Rotzschke et al. teach "Allele-specific consensus motifs can be used to scan protein sequences to

Art Unit: 1644

identify T cell epitopes." (see page 453, first column, third paragraph) whilst Boon et al. teach that MAGE-3 is a TRAP which encodes TRA (tumor rejection antigen) wherein it is desirable to elucidate the identity of the actual peptide recognized by the CTL (see columns 23-26 and columns 3-4).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 50,56,57,59,61,62 are rejected under 35 U.S.C. 102(e) as being anticipated by Boon (US Patent 5,342,774).

In light of newly amended claim 50, the composition claims are now interpreted as encompassing the peptide KVAELVHFL attached to other amino acids, including intact MAGE 3.

Boon et al. teach MAGE 3, wherein the peptide KVAELVHFL is found in said protein (see Examples 23, 25, column 24, fourth paragraph). Boon et al. teach a nucleic acid encoding MAGE-3 with the appropriate delineated coding sequence (see Figure 20). The MAGE-3 amino acid sequence (derived from the aforementioned nucleic acid using the art known genetic code) contains peptide KVAELVHFL. Boon et al. teach a pharmaceutical composition containing said protein (see column 25, first paragraph) wherein said composition would contain other ingredients (such as a fluid) which would be encompassed by the term carrier or pharmaceutically acceptable carrier. The additional MAGE 3 amino acids would be encompassed by the term "spacer or linker amino acids" and said molecule contains one or more different peptides.

11. No claim is allowed.

Art Unit: 1644

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1644

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644


RON B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 (600)